

## REMARKS/ARGUMENTS

This is in response to the official action dated December 13, 2007. Reconsideration is respectfully requested.

### Specification

Applicant respectfully submits that the Substitute Specification received (date stamped) by the USPTO on January 3, 2007 be entered (a copy of the first page is enclosed herewith proof of receipt. Applicant respectfully requests the USPTO to replace the specification with the specification received on January 3, 2007. Applicant further submits that the substitute specification includes no new matter.

### Rejections under 35 USC 101

Claims 1-2 and 4-14 were rejected for being directed to non-statutory subject matter. According to the Examiner, the claimed invention does not transform an article or physical object to a different state or thing outside a computation device. The Examiner further contends that the claimed invention does not produce a useful, concrete and tangible result.

The applicant submits that the notion of “physical transformation” is not an invariable requirement but merely one example of how a mathematical algorithm may bring about a useful application. The claimed invention does correspond to a useful, concrete and tangible thing, that is the identification of an optimal genetic test order, and therefore it constitutes a practical application of an abstract idea.

In determining whether the claim is for a “practical application”, the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete”.

The tangible requirement does not mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. The tangible requirement means that the claim must define a practical application to produce a real-world result. It is the result that must be shown to be tangible.

The invention produces a “concrete” result when it has a result that can be substantially repeatable.

The applicant respectfully submits that the claims recite an invention that is “useful, tangible and concrete.” The claims recite a process, or a computer readable medium comprising instructions to perform the process, or a system for performing the process, for determining an optimal test order for diagnosing mutations that relate to a disease. The optimal genetic test order allows for the most cost-effective use of genetic screening techniques for the particular disease in a patient. This is a specific, substantial and credible result with practical and commercial applications. Thus, it is submitted that the subject matter is statutory.

**Rejections under 35 USC 112, second paragraph**

The Examiner has rejected claims 4-11 for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. Specifically, the rejection of claims 4-11 relates to an overlap of two different classes of inventions. The rejection of claim 12 appears to relate to the “recommendation” in step e).

The applicant has amended claim 4 to clarify that the claim is directed to a process.

The applicant has amended claim 12 by replacing “a recommendation” with “the optimal test order.”

Thus, applicant submits that the indefiniteness rejection has been overcome and further submits that the rejection should be withdrawn.

**Anticipation – 35 USC §102**

The Examiner has rejected claims 4-14 as anticipated by Bapat *et al.* (Gut, 44:698-703 (1999)) (“Bapat”).

Applicant traverses this rejection. Bapat does not disclose each feature of the present invention. The Examiner notes that, in Bapat, the decision tree algorithm is used in cost comparison analysis of the mutation testing strategy versus clinical screening strategy [including baseline model and sensitivity model].

The Examiner further notes that the comparison by Bapat reveals that genetic testing approach costs less than that of the conventional clinical strategy over a wide variety of variables, which

makes Bapat recommend that “on the basis of economic variables alone, molecular genetic testing was the method of choice.”

The present invention, on the other hand, discloses a method and system of determining an optimal genetic test order of several genetic tests for diagnosing mutations that relate to a disease. The present invention does not relate to a comparison of genetic testing versus clinical testing. Instead, it recites a method and system for an optimal strategy of identifying which next analytic step (assay or genetic test) minimizes the cost for each step of any feasible history.

The optimal strategy is determined by:

- Listing every known disease-associated mutation in a target gene and the relative frequency of occurrence;
- For each mutation listed and each possible combination of molecular assays available, identifying which combinations of assays conclusively identify each known mutation;
- Applying a decision tree algorithm of the available strategies or combination of assays in order to identify the optimal, most cost-effective sequence of available assays by:
  - Counting the expected cost to perform each assay and confirm any mutation that might be identified by that assay;
  - Counting the number of indicators of mutations (“hits”) for each remaining assay;
  - For each available assay, dividing the number of hits by the cost; the next assay to perform is that with the highest ratio of hits to cost;
  - If, after performing the next assay, a conclusive mutation analysis has not been reached, recalculating the expected assay costs and repeating the above steps until a conclusive mutation diagnosis is achieved.

Bapat does not disclose a cost-minimizing use of several genetic tests for a particular disease – rather it takes as given the cost of the genetic tests.

Thus, applicant submits that Bapat does not anticipate the rejected claims and the rejection should be withdrawn. .

#### **Obviousness – 35 USC §103**

The Examiner is rejecting Claims 1-2 under 35 U.S.C. 103(a) as being unpatentable over Bapat et al. (Gut, Vol 44, pages 698-703, 1999) and in light of common general knowledge. Applicant

respectfully submits that, in light of the arguments above, claims 1-2 are patentable for at least the same reasons as claims 4-14. Thus, applicant submits that this rejection was overcome and that it should be withdrawn.

**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Respectfully submitted,  
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